REMARKS

Claim Rejections - 35 USC §112 (November 11, 2002 Final Office Action)

New claims have been added which obviates the §112 rejections in the previous office action. These new claims basically have the language of the original claims. No new matter has been added.

Claim Rejections – 35 USC §103

Claims 21, 26 and 27 recites using an urine sample in detecting an early stage renal diseases. Hoffman et al. does not teach that L-PGDS accumulates in urine. Therefore, it would not have been obvious to a person of ordinary skill in the art that the detection of L-PGDS in urine can be used for detecting early stage renal diseases.

The claimed method of the present application is directed to detecting an early-stage renal disease. Hoffman et al. describes that "Since β-TP accumulates more significantly in serum in pathological conditions…., we suppose that especially in early diagnosis of renal disease…" However, Hoffman et al. did not study the correlation between L-PGDS and early renal disease and did not define what the condition of the early renal disease state is. Hoffman et al. merely speculates on the application.

In claim 22 and 23 below, the recitation "prior to diagnosis of early nephropathy" is added. Hoffman et al. has not recognized that early stage renal diseases can be detected prior to diagnosis of early nephropathy. Experiments were carried out by the present inventors to show that the detection of early stage renal diseases are possible before the onset and the detection of the early nephropathy (see Example 4 on page 22). Hoffman et al. has not shown or evidenced this. Thus, a person or ordinary skill in the art would not have found obvious the present invention as claimed in claims 22 and 23.

Furthermore, the recitation "without purifying the human lipokalin-type prostaglandin D synthase" has been added in claim 23. The specification of the present application refers to Hoffman et al. on page 8 and describes that "their assay method is complicated. Briefly, they purify L-PGDS from serum samples...." Hoffman et al. describes that "[i]n order to confirm the elevated concentration of β –TP in the sera of dialysis patients, β –TP was quantitatively purified with sera of five further patients by immunoaffinity chromatography," at lines 5 to 8 on page 500. This description indicate that a sample is purified before being assayed. On the other hand, the specification of the present application describes"... serum samples and... spotted urine samples were used. After these samples were appropriately diluted with the blocking solution..." on pages 16 to 17. This description indicates that a sample does not have to be purified. Therefore, the claimed method is unobvious over Hoffman's et al. because the claimed method is easier to carry out than Hoffman's method.

For the foregoing reasons, new claims would not have been obvious to a person of ordinary skill in the art. It is requested that all pending claims be allowed.